IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [49] 1:22-cv-00490-LMM [46] 1:22-cv-01583-LMM [57]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on a Motion to Exclude Certain Opinions of Jonathan P. Jarow, M.D., from evidence offered in defense against claims asserted by bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs"). Upon due consideration, the Court enters the following Order.

I. BACKGROUND

Paragard is an IUD that is implanted into a patient's uterus by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is

supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008 and held it until the NDA was acquired by Cooper on November 1, 2017.[1]

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected for the removal of her Paragard to be simple and easy. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

Dr. Jarow is a licensed medical doctor with former employment experience at the FDA. He is currently employed as an expert consultant to pharmaceutical

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

companies. Jarow CV (Dkt. No. [49-1]).[2] Defendant retained Dr. Jarow as a regulatory expert. Dkt. No. [81] at 4. Plaintiffs seek to exclude Dr. Jarow's opinions that (1) Defendant could not have added warnings to the Paragard label via the Changes Being Effected ("CBE") process because it did not receive any "newly acquired information" that would have allowed it to do so, and (2) that adverse event reports of Paragard breakage remained constant from 2005 to 2016.

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and,
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharm., 509 U.S. 579, 591 (1993) (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998), reh'g and reh'g en banc denied, 172 F.3d 884 (1999).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and

methods. Daubert lists factors for courts to consider, including: (1) "whether [the theory or technique] can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "the known or potential rate of error," and (4) "general acceptance" of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply on ly those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden

of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotations omitted). "Quite the contrary, 'vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (internal alteration omitted).

III. DISCUSSION

A. Dr. Jarow's opinion that Defendant could not have used the CBE process to strengthen the breakage warnings

In adjudicating Defendant's motion for summary judgment on preemption grounds, the Court determined that there was newly acquired information that would have allowed Defendant to use the CBE process to add a breakage warning

to the Paragard label.[3] Dkt. No. [137] at 9-13. Whether Defendant could have used the CBE process to strengthen the breakage warnings is therefore no longer at issue in this case. Plaintiffs' motion to exclude testimony on the issue is thus moot.

B. Dr. Jarow's opinion that adverse event reports of breakage remained constant from 2005 to 2016

Plaintiffs also argue that Dr. Jarow's opinion that adverse event reports of breakage remained consistent in type, severity, and frequency from 2005 to 2016 should be excluded. They contend that Dr. Jarow did not demonstrate reliable methodology, and they fault him for failing to address a 2015 FDA submission created by Teva Head of Pharmacovigilance, Dr. Siyu Liu, in which Dr. Liu identified device breakage as a reportable adverse event, noted that breakage without embedment was possibly causally associated with Paragard, and determined that breakage was not already adequately discussed and included under the Warnings, Precautions, or Adverse Reactions sections of the Paragard label. Dkt. No. [49] at 7-11. The Court agrees with Plaintiffs that the testimony is not the product of reliable principles and methods and therefore should be excluded.

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[3] Notably, Defendant did not cite Dr. Jarow's labeling opinions in its summary judgment briefs or the associated statements of material fact. See Dkt. No. [42, 42-1, 92, 92-1].

While Defendant points to Dr. Liu's FDA submission among the more than 1,000 documents in Dr. Jarow's Materials Considered List, Defendant does not point to any portion of the report where Dr. Jarow analyzes or even references the submission. During his deposition, Dr. Jarow also did not remember Dr. Liu's submission, and Defendant made no attempt to rehabilitate his testimony by refreshing his recollection.

Moreover, the paragraphs of Dr. Jarow's report that Defendant contends show that he "employed a careful and well-explained methodology in developing his opinion that reports of breakage received by Teva and Cooper have been consistent in type, severity, and frequency" do no such thing. See Dkt. No. [49-3] ¶¶ 66-115. If anything, they indicate that reports of breakage increased over time. See, e.g., id. ¶¶ 97, 104, 105, 106, 110, 113; see also id. ¶ 132. Dr. Jarow also conceded in his deposition that the data he relied upon for a yearly count of the breakage reports for the 2005 to 2010 time period—the period predating the placement of Plaintiffs' Paragards—came from the Kessler report and were not meant to be an accurate count of the number of breakage events reported each year. Deposition of Jonathan P. Jarow, M.D. ("Jarow Dep.") at 190-93; see also Deposition of Dr. David Kessler ("Kessler Dep.") at 29-30 (explaining that he had conducted a review of Periodic Adverse Drug Experience Reports ("PADERs") but that there was "no representation that [he] found everything. That was not the goal."); Dkt. No. [42-19] at 40 (statement in Kessler Report that the report

was not intended to provide an exact or accurate count of Paragard breakage events by year, that his methodology instead focused on determining whether manufacturers had evidence of breakage reports in the relevant years, and that the numbers presented were likely undercounts due to inconsistent coding and underreporting).

The Court therefore finds that Dr. Jarow's opinion that adverse event reports of breakage remained consistent in type, severity, and frequency from 2005 to 2016 is not the product of reliable principles and methods. He therefore will not be permitted to offer such testimony.

IV. CONCLUSION

Plaintiffs' Motion to Exclude Certain Opinions of Jonathan P. Jarow, M.D., from evidence in the bellwether cases is **GRANTED IN PART AND DENIED AS MOOT IN PART**, as set out above.

IT IS SO ORDERED this 7th day of January, 2026.

Leigh Martin May
Chief United States District Judge